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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* CHARLES BENNETT Plaintiff-Relator, v. BAYER CORPORATION, *et al.*, Defendants.	Civil Action No. 2:17-cv-04188-ES-JBC MOTION DATE: December 5, 2022 **DOCUMENT FILED ELECTRONICALLY**

MEMORANDUM IN SUPPORT OF BAYER CORPORATION AND MERCK & CO., INC.'S MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

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Pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), Defendants Bayer Corporation ("Bayer") and Merck & Co., Inc. ("Merck") submit this memorandum in support of their motion to dismiss Relator Charles Bennett's Second Amended Complaint ("SAC") [Dkt. 59].

INTRODUCTION

Notwithstanding the benefit of the Court's detailed opinion dismissing the First Amended Complaint ("FAC"), Relator's third attempt to plead a False Claims Act ("FCA") violation still falls woefully short. Like its predecessor, the SAC fails at the threshold on the element of materiality because it "does not identify any information concerning the safety of Cipro . . . that the [U.S. Food and Drug Administration ("FDA")] was unaware of." *U.S. ex rel. Bennett v. Bayer Corp.*, No. 17-cv-4188, 2022 WL 970219, at *10 (D.N.J. Mar. 31, 2022) ("*Bennett I*"). Indeed, the SAC "concede[s] the opposite," *id.*—that "*the FDA's own scientists* uncovered the *full extent* of [Cipro] side effects." *See* SAC ¶ 104 (emphases added). Nor does Relator dispute that FDA, with knowledge of the purported safety issues Relator alleges, never withdrew approval of Cipro®, and the Centers for Medicare and Medicaid Services ("CMS") continued to pay claims for the drug. Thus, this case yet again "stands almost on all fours with" *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), and the Court should dismiss the SAC for failure plausibly to plead materiality for the same reasons it dismissed the FAC. *See Bennett I*, 2022 WL 970219, at *10.

In addition, although Relator has apparently abandoned his implied false certification theory in favor of a "fraudulent inducement" theory, he still fails plausibly to plead the FCA elements of falsity and causation. First, "fraudulent inducement" is not legally viable in the absence of a contract between the defendant and the government, *In re Plavix Mtkg., Sales Practice & Prods. Liab. Litig. (No. II)*, 332 F. Supp. 3d 927, 952-53 (D.N.J. 2017), and Relator alleges no such contract here. Second, even if fraudulent inducement were a viable theory here, Relator does

not adequately plead it. He still fails to allege "what Bayer [and Merck] . . . actually said about Cipro . . . and [its] adverse effects" that was allegedly false or identify "what specific information Bayer [and Merck] . . . failed to disclose." *Bennett I*, 2022 WL 970219, at *8. Instead, Relator merely speculates that, because additional safety information emerged years after Cipro's approval, Bayer *must have* concealed safety information when initially seeking FDA's approval for the drug. But rather than identify a single fact of which Bayer and Merck were purportedly aware but hid from FDA, Relator instead relies entirely on impermissible supposition and guesswork. *See, e.g.*, SAC ¶ 84 (Defendants' "dismissive attitude" "*suggests* that Defendants knew of the dangerous adverse . . . events and hid and/or downplayed the side effects" (emphasis added)); *id.* ¶ 95 (labeling change *"suggest[ed]* that Defendants actively worked to downplay the mental health side effects" (emphasis added)). These groundless musings are insufficient to plead fraudulent inducement plausibly, let alone with particularity.

Finally, the FCA's statutory public disclosure bar independently requires dismissal. Relator's allegations rely entirely on public information that disclosed substantially similar "allegations or transactions" to those Relator seeks to repackage as FCA violations. Nor can Relator qualify for the "original source" exception to the bar because his allegations add nothing to the publicly disclosed information.

For these reasons, the Court should dismiss the SAC in its entirety, with prejudice.

BACKGROUND

The Court is familiar with the factual background and procedural history of this dispute. On June 9, 2017, Relator filed this *qui tam* action under seal against Bayer and Merck. *Bennett I*, 2022 WL 970219, at *4. On August 10, 2018, Relator filed the FAC, which added three Johnson & Johnson entities as defendants ("J&J Defendants"), and alleged that Bayer and Merck "misbrand[ed]" Cipro because, in Relator's view, the drug's labeling did not go far enough to warn

of certain adverse events—particularly, Fluoroquinolone-Associated Disability ("FQAD"), mitochondrial toxicity, and psychiatric effects. FAC ¶ 4-5. The government declined to intervene. Dkt. 8. In March 2021, Bayer, Merck, and the J&J Defendants moved to dismiss the FAC under Rules 9(b) and 12(b)(6). The Court granted those motions in March 2022, dismissing the FAC without prejudice. *Bennett I*, 2022 WL 970219. Relator filed the SAC on May 31, 2022. Dkt. 59.

I. Regulatory Framework

FDA is the exclusive expert federal agency charged with regulating prescription drugs. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). Before marketing a new drug, a pharmaceutical manufacturer must submit and receive FDA's approval for a New Drug Application ("NDA"). 21 U.S.C. § 355(a); *see* SAC ¶ 49. An applicant must provide detailed technical information in an NDA, including proposed labeling, the drug's intended use and clinical benefits, and a summary of clinical data and statistical analysis of its efficacy. 21 C.F.R. § 314.50. FDA may deny approval for several reasons, including if "there is insufficient information about the drug to determine whether [it] is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling." 21 C.F.R. § 314.125(b)(4). FDA will approve the drug if, after its detailed assessment, "it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. §§ 314.105(c), (d). FDA's approval process involves a "multi-year process of study and testing," SAC ¶ 51, including a "comprehensive scientific evaluation of the product's risks and benefits." 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006); *see* SAC ¶ 52.

After approval, FDA remains responsible for monitoring the drug's safety and efficacy. SAC ¶ 50. Manufacturers must file post-marketing reports of "[a]dverse drug experience[s]" with the agency as well as other information that "might affect the safety, effectiveness, or labeling of the drug." 21 C.F.R. § 314.80-81; SAC ¶ 54. FDA's adverse event reporting system is known as

"FAERS." SAC ¶ 101. FDA also regulates the labeling of prescription drugs and may request labeling changes if it becomes aware of new safety information. 21 U.S.C. § 355(o)(4).

Private citizens who believe that FDA has not considered certain safety information in its approval or continued assessment of a drug can petition FDA—as Relator did here, *three times*—to take administrative action. *See* 21 C.F.R. § 10.30 (outlining citizen petition process, including appeal procedures that Relator did not pursue here). That process—not an FCA lawsuit—is the appropriate vehicle for a private individual to voice his disagreement with FDA's judgment and decision-making. *U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, Nos. 10-11043, 11-10343, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012). If FDA finds that a manufacturer failed to disclose relevant safety information, the agency is empowered to pursue a range of sanctions, including withdrawing approval of the drug, injunctive relief, civil monetary penalties, and referral for criminal prosecution. 21 U.S.C. §§ 332, 333(a), 333(f)(3)(A), 355(e). By affording FDA a "variety of enforcement options," Congress intended to "allow [the agency] to make a measured response to suspected fraud." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

II. Cipro and the Relevant FDA Actions

Bayer submitted the NDA for Cipro in 1985. As required by law, the NDA disclosed, among other things, the clinical investigations of the drug, including information related to its safety and effectiveness. *See* SAC ¶ 53 (citing 21 C.F.R. § 314.50). FDA approved Cipro in 1987 after a multi-year review, SAC ¶¶ 28, 46, and the drug has undergone extensive review and monitoring of its safety profile by FDA since approval. *See id.* ¶¶ 70, 75, 85, 90, 92, 94-95.

A. 2013 FDA Report and Labeling Changes

In April 2013, in connection with its ongoing review and careful assessment of Cipro's safety and efficacy, FDA published a report regarding "an association between fluoroquinolone antibiotic use and disabling peripheral neuropathy," which was based on information from

FAERS. *See* Ex. A,[1] 2013 FDA Report at 3-4[2]; SAC ¶ 75. The FDA report, while acknowledging that peripheral neuropathy had already been added to fluoroquinolone labeling in 2004, recommended updating the labeling to include "language reflecting the rapid onset and possible permanence of peripheral neuropathy" and "language to discontinue the fluoroquinolone immediately with the first symptoms of peripheral neuropathy, unless the benefit of continued treatment . . . outweighs the risk." Ex. A at 12, 13. Based on the report's findings, FDA announced in August 2013 that it was requiring updates to the labeling for all fluoroquinolones, including Cipro, to "better describe the serious side effect of peripheral neuropathy" and to state that the condition "may be permanent." Ex. B, 2013 FDA Press Release. FDA further stated that it would "continue to evaluate the safety of drugs in the fluoroquinolone class." *Id.*

B. Relator's 2014 Citizen Petitions

Ten months later, in June 2014, Relator filed his first of three citizen petitions with FDA, asking the agency to "review [fluoroquinolone] labeling regarding possible mitochondrial toxicity, based on his reading of the 2013 FDA pharmacovigilance report . . . in light of his own research." SAC ¶ 76; Ex. C, June 2014 Citizen Petition. The petition largely parroted the findings of FDA's own report, included references to other published studies and to the likely under-reporting of "potential Mitochondrial Toxicity Adverse Events," and requested that FDA revise fluoroquinolone labeling to warn against "possible mitochondrial toxicity." Ex. C at 1-2, 8.

[1] The Exhibits referenced herein are attached to the Declaration of Paul J. Fishman.

[2] The Court may consider on a motion to dismiss any documents that are "integral to and/or . . . explicitly relied upon by the [SAC]," as well as "matters of which a court may take judicial notice," without converting the motion into one for summary judgment. *Winer Family Tr. v. Queen*, 503 F.3d 319, 328 (3d Cir. 2007) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007)). As this Court has recognized, it may take judicial notice of public records, including "filings" to government agencies, "decision letters of government agencies and published reports of administrative bodies." *Bennett I*, 2022 WL 970219, at *10 (citation omitted).

Relator filed yet another citizen petition with FDA in September 2014, "informing the agency of some of his research findings among the more than 200 patients who suffered serious adverse psychiatric events" he claims were not listed on the medication labels, and asking FDA to review fluoroquinolone labeling, this time based principally on Relator's review of FAERS data. SAC ¶ 77; Ex. D, September 2014 Citizen Petition. Relator argued the existing fluoroquinolone labeling was inadequate because it listed "psychiatric effects" "under the 'Central Nervous System Effects' heading," instead of including a stand-alone heading for psychiatric effects. Ex. D at 2. Relator's citizen petitions were publicly docketed and are publicly available on www.regulations.gov.[3]

C. FDA's November 2015 Public Hearing Regarding Fluoroquinolones

In November 2015, based on its review of relevant data, published studies, and the 2013 FDA report, FDA held a Joint Meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee "to discuss the benefits and risks" of using fluoroquinolones to treat sinusitis, bronchitis, and urinary tract infections. Ex. E, 2015 FDA Advisory Committee Meeting Briefing at 10-11; *see* SAC ¶ 85. The FDA briefing materials for the meeting noted that FDA had identified as an "emerging safety issue[]" "symptoms involving different body sites that often interfere with activities of daily living and can persist," which some had termed "Fluoroquinolone-Associated Disability" or "FQAD." Ex. E at 9, 95; *see* SAC ¶ 3 (defining FQAD). Dr. Deborah Boxwell, the lead author of the 2013 FDA report, presented at the meeting, along with several other leading physicians and researchers. Ex. E at 12. Relator himself

[3] Although Relator's petitions focus on Levaquin®, he has acknowledged that, "historically, label changes to one [fluoroquinolone] resulted in label changes to the other [fluoroquinolones] so that these Citizen Petitions applied to . . . Cipro, as well." FAC ¶ 51. And in ruling on Relator's September 2014 citizen petition, FDA explained that it "considered [Relator's] requests in light of systemic fluoroquinolones (i.e., ciprofloxacin . . .) as a class of drugs." Ex. J, FDA Final Decision at 1 n.1, Dkt. No. FDA-2014-P-1611 (July 10, 2018).

attended and even participated in the meeting, speaking about fluoroquinolone "neurological and psychiatric events" from his research and noting that he had filed two citizen petitions "to try to get the product label to be updated." SAC ¶ 85; Ex. F, 2015 FDA Advisory Committee Meeting Transcript at 217:20-219:18. Immediately following the meeting, the FDA Advisory Committee recommended changes to the labeling of Cipro and other fluoroquinolones. SAC ¶ 90.

D. 2016 Label Changes and FDA's Denial of Relator's First Citizen Petition

A few months later, in July 2016, FDA approved Cipro's revised labeling. *Id.* ¶ 94. In the press release announcing its approval, FDA stated that "[f]luoroquinolones have risks and benefits," and "[i]t's important that both health care providers and patients are aware of both the risks and the benefits . . . and make an informed decision about their use." Ex. G, July 2016 FDA Press Release; *see* SAC ¶ 94. The press release further advised that, based on "new safety information" discussed at the November 2015 meeting, the revised labeling would state that for certain conditions—in particular, sinusitis, bronchitis, and urinary tract infections—"fluoroquinolones should be reserved for use in patients . . . who have no alternative treatment options." Ex. G. FDA did not require that the labeling specifically reference "FQAD," nor did it require a stand-alone warning for psychiatric side effects. SAC ¶ 94.

Although Relator continues to omit this fact from his pleading, FDA *denied* Relator's first citizen petition at the same time the agency announced the required updates to the Cipro label. Ex. H, FDA Final Decision, Dkt. No. FDA-2014-0856 (May 12, 2016). In its denial, FDA explained that it had specifically considered and rejected Relator's request to add "mitochondrial toxicity" to the product labeling because it did "not consider possible mitochondrial toxicity in itself a specific clinical adverse reaction." *Id.* at 7. FDA went even further and concluded that Relator's requested labeling changes lacked "[]adequate scientific support" and would "not help a clinician or patient identify or treat a particular adverse reaction." *Id.* at 7, 10, 13.

E. 2018 Label Changes and FDA's Response to Relator's Second Citizen Petition

In July 2018, FDA announced additional Cipro labeling changes "to strengthen the warnings about the risks of mental health side effects and serious blood sugar disturbances." Ex. I, FDA July 2018 Press Release; *see* SAC ¶ 95. Again, although the SAC does not mention it, FDA simultaneously issued a decision on Relator's second citizen petition, noting that the agency was already "taking action to require certain changes to the labeling of . . . fluoroquinolone antibacterial drugs to reflect new safety information," and otherwise *denied the petition.* Ex. J, 2018 FDA Final Decision at 2. In particular, FDA explained that it had performed its own analysis and added to the labeling certain side effects identified in Relator's second citizen petition, *id.* at 6-10, but it declined to make additional changes Relator requested due to a "lack of reasonable evidence." *Id.* at 9. For example, FDA denied Relator's requests to separate psychiatric side effects from "central nervous system effects" and to add psychiatric effects to the boxed warning. *Id.* at 12.

F. Relator's 2019 Citizen Petition and FDA's Denial

In June 2019, Relator filed yet another citizen petition, once again asking FDA to change the labeling of fluoroquinolones. Ex. K, 2019 Citizen Petition. In particular, Relator requested that FDA add "FQAD" and psychiatric adverse events to the product's Black Box Warning and implement additional risk mitigation measures. *Id.* at 1. FDA denied the petition in August 2020 and declined to make further labeling changes. In concluding that the existing labeling adequately warned of the adverse events raised in Relator's petition, FDA noted that "FQAD" "is not accepted medical terminology and is not used in clinical practice." Ex. L, 2020 FDA Decision at 1 n.2, 5-7. FDA made clear that the product's "risks are adequately communicated in [the] approved labeling." *Id.*

* * *

Despite Relator's third attempt at a viable pleading, accompanied by an effort to advance a new (albeit still not viable) theory of liability, nowhere in the SAC does Relator identify any specific safety information that Bayer or Merck allegedly withheld from FDA regarding Cipro – either before or after approval. On the contrary, Relator concedes that "Relator and *the FDA's own scientists uncovered the full extent of FQ side effects*" and that FDA made labeling changes as a result. SAC ¶ 104 (emphasis added); *see also id.* ¶ 25 (alleging that Relator's research, which was provided to FDA and publicly disseminated, uncovered the "full extent of the dangers of FQs"). Relator does not allege—nor could he—that FDA at any point withdrew its approval for the drug. Instead, the SAC makes clear that FDA has engaged in ongoing and careful review of Cipro's safety and efficacy and has renewed the drug's approval while updating its labeling over time. Critically, the SAC also does not allege that CMS has ever refused to reimburse claims for Cipro based on the safety information Relator alleges. The opposite is true: Medicare and Medicaid have reimbursed, and continue to reimburse, claims for Cipro to this day.[4]

III. Procedural History

A. This Court's Decision in *Bennett I*

In March 2022, the Court dismissed Relator's FAC for failure adequately to plead falsity and materiality. With respect to falsity, the Court held that the FAC "clearly pursue[d] a false certification theory," and that Relator's false certification allegations failed the plausibility standard. *Bennett I*, 2022 WL 970219, at *7. The Court also squarely addressed Relator's belated attempt in his opposition brief to recast his claims as "fraudulent inducement." *Id.* at *7-8. The Court acknowledged that there was a question about whether Relator's "fraudulent inducement

[4] *See* CMS, Drug Products in the Medicaid Drug Rebate Program, https://tinyurl.com/2vme4f37; CMS, 2020 Table of Drugs, https://go.cms.gov/3phGS0h.

theory is viable in the absence of a contractual relationship," *id.* at *7 n.3, but declined to decide that issue because Relator's allegations failed to plead fraudulent inducement in two important respects. First, the Court explained that the FAC's "vague[] refer[ences] to statements of 'Defendant' or 'Defendants' . . . amount[ed] to an impermissible group pleading." *Id.* at *7. The FAC's "fail[ure] to distinguish between Bayer and J&J—two distinct entities who sold different drugs" fell far short of "even Rule 8(a)(2)'s notice pleading standard, let alone the particularity standard of Rule 9(b)." *Id.* Second, the Court held that the FAC did not adequately allege either "what Bayer . . . actually said about Cipro . . . and [its] adverse effects" that was allegedly false or "what specific information Bayer . . . failed to disclose and why [it] w[as] under a duty to disclose that information even though . . . the FDA was made aware of all the information put forth in the [FAC]." *Id.* at *8.

With respect to Relator's allegations on materiality, the Court concluded that, although "Relator purport[ed] that the FDA was unaware of the potential safety issues of Cipro," he did not allege "there was safety information that was unknown to the FDA," and, indeed, "appear[ed] to concede the opposite—that he and 'the *FDA's own scientists* uncovered the *full extent* of FQ side effects.'" *Id.* at *10. This exact phrase, which first appeared in Relator's opposition brief and was central to the Court's holding, appears now in the SAC. *See* SAC ¶ 104. The Court held that "[t]his case thus stands almost on all fours with *Petratos*: (i) the FDA was aware of all the safety information concerning [Cipro]; (ii) the FDA declined to change the label as Relator would like; (iii) CMS continued to pay reimbursements; and (iv) the Government declined to intervene in the qui tam action." *Id.* (citing *Petratos*, 855 F.3d at 490). The Court further held that the Cipro labeling changes "cut[] further against materiality" because "FDA made those labeling changes *based on the same information* that Bayer . . . allegedly failed to disclose—yet the FDA

conspicuously declined to include the side effects that Relator faults Bayer . . . for not including." *Id.* "Thus, while the FDA's changes 'show that the FDA was paying attention,' the 'lack of any further action also shows that the FDA viewed the information, including that furnished by Relator, differently than Relator does.'" *Id.* (quoting *U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017)) (brackets omitted).

B. Relator's Second Amended Complaint

Relator now attempts to salvage the FAC's deficient allegations merely by repeating them in the SAC and recasting them as "fraudulent inducement."[5] He alleges that "Defendants" "willfully fail[ed] to disclose the existence, frequency, and severity of permanent and debilitating side effects" from fluoroquinolones. SAC ¶ 3. He further alleges that "[f]rom research and development of their respective FQ products . . . Defendants have known the true severity of the dangers of FQs," but have "covered-up unfavorable data, circulated misleading half-truths, and/or outright denied the existence, frequency, and severity of [fluoroquinolone] side effects." *Id.* ¶ 6-7. Relator, however, does not and cannot plead any allegations about a contractual relationship between the government and either Bayer or Merck. He also fails to identify a single fact of which Bayer and Merck were purportedly aware but failed to disclose to FDA, or plead a single allegedly false statement that Bayer or Merck made. The best Relator can muster are allegations that Bayer both "intentionally disaggregated individual symptomatic components of serious multi-system syndromes in its NDA submitted to the FDA," *id.* ¶ 57, and also did the opposite: "failed to aggregate" multiple side effects, *id.*¶ 63. Not only are these inherently inconsistent allegations

[5] Although Relator purports to pursue only a fraudulent inducement theory, the SAC includes the same allegations of post-FDA approval conduct, *see, e.g.*, SAC ¶¶ 11, 81-82, 86-89, that this Court explained reflected only an "implied false certification" theory, and were insufficient to state a claim under that theory. *Bennett I*, 2022 WL 970219, at *9.

wholly lacking in specifics, but FDA knew about, considered, and rejected these very points when Relator made them *to FDA* in his own citizen petitions. The remainder of the SAC simply recycles the FAC's deficient allegations, asserting in vague and conclusory fashion that, after Cipro was approved, "Defendants" "intentionally and deceitfully misrepresent[ed] the dangers of . . . Cipro" and "doggedly 'stood by the product'" after FDA's 2013 report and 2015 Advisory Committee Meeting. *See, e.g.*, SAC ¶¶ 65, 81. Moreover, because the SAC does not identify any new source of safety information that was unknown to FDA or contain a single allegation that CMS stopped paying Cipro claims after gaining such knowledge, Relator's pleading not only fails to allege materiality—it "establish[es] conclusively the *lack* of materiality." *U.S. ex rel. Hlywiak v. Great Lakes Educ. Loan Servs., Inc.*, No. 20-cv-13590, 2022 WL 787957, at *11 (D.N.J. Mar. 15, 2022).

ARGUMENT

I. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), a relator's complaint must "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A relator's allegations must allow the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged"; it is not enough for a complaint to raise only the possibility that the defendant acted unlawfully. *Id.* . FCA allegations must also satisfy Rule 9(b)'s heightened pleading requirements with respect to both the alleged scheme and its nexus to the submission of false reimbursement claims. *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 & n.3 (3d Cir. 2014).

II. The SAC Should Be Dismissed Because Relator Fails Adequately to Plead the Essential Elements of an FCA Violation.

To state a claim under the FCA, a relator must properly plead four distinct elements: "falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487. The Court should

dismiss the SAC in its entirety because: (1) controlling Third Circuit precedent makes clear that any purported concealment of safety information was *not material* to the government's decisions to pay claims for Cipro; (2) Relator's fraudulent inducement theory of FCA liability is not legally viable, plausible, or pled with requisite particularity; and (3) Relator's conclusory off-label marketing allegations are woefully insufficient under Rule 9(b).

A. Like the FAC, the SAC Concedes That Any Alleged Concealment of Safety Information Was Not Material.

"[A] misrepresentation . . . must be material to the Government's payment decision in order to be actionable under the [FCA]." *Petratos*, 855 F.3d at 489 (quoting *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 181 (2016)). As this Court has recognized, "[t]he standard for materiality . . . is 'rigorous' and 'demanding.'" *Bennett I*, 2022 WL 970219, at *8 (quoting *Escobar*, 579 U.S. at 192, 194, and citing *Petratos*, 855 F.3d at 492). To meet the "heightened" materiality standard, a relator must plead facts sufficient to allege plausibly that the government "would not have reimbursed . . . claims" for a drug had it been aware of the defendant's alleged misrepresentations. *Petratos*, 855 F.3d at 490, 492. Like its predecessor, the SAC plainly fails this test: The regulatory history it (selectively) pleads demonstrates that the government was aware of and carefully considered the safety information Relator alleges that Bayer and Merck concealed, all while continuing to reimburse claims for the drug. As a result, the Court should dismiss the SAC for failure adequately to plead materiality. *See Plavix*, 332 F. Supp. 3d at 946 (dismissing for failure to plead materiality where "specific allegations . . . belie[d] conclusory facts" that alleged violations were material).

The Third Circuit's decision in *Petratos* "control[s] the outcome" here, and requires dismissal for the same reasons the Court dismissed the FAC. *See Plavix*, 332 F. Supp. 3d at 947. As the Court is aware, the relator in *Petratos* alleged that a medical device manufacturer

suppressed safety data, which caused doctors to certify incorrectly that a drug was "reasonable and necessary" for certain at-risk Medicare patients. 855 F.3d at 485. In affirming dismissal under Rule 12(b)(6) for failure to plead materiality, the Third Circuit explained that "there [were] no factual allegations showing that CMS would not have reimbursed these claims had these alleged [safety] reporting deficiencies been cured." *Id.* at 490 (brackets omitted). Indeed, the relator's allegations showed precisely the opposite—that "CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance." *Id.* The relator admitted that he disclosed "material, non-public evidence of [the defendant's] campaign of misinformation" to FDA, and the agency nonetheless maintained its approval of the device. *Id.* That continued approval, in turn, kept the device eligible for reimbursement under Medicare and Medicaid. *Id.* Because the facts as pled effectively "concede[d] that the expert agencies and government regulators ha[d] deemed the[] violations insubstantial," the court held it was "[in]appropriate for a private citizen to enforce these regulations through the [FCA]." *Id.*

Here, just like in *Petratos*, Relator admits that FDA had actual knowledge of the safety information alleged in the SAC: that Cipro purportedly causes mitochondrial toxicity, FQAD, and psychiatric effects. Indeed, the SAC expressly admits that Relator "and *the FDA's own scientists* uncovered the *full extent* of FQ side effects." SAC ¶ 104 (emphasis added); *see Bennett I*, 2022 WL 970219, at *10 (interpreting the same assertion in Relator's opposition brief as a "conce[ssion]" there was no "safety information that was unknown to the FDA"). Similar to the FAC, the SAC relies on safety information from (1) FDA's 2013 report, SAC ¶ 75; (2) FAERS data reported to FDA, *id.* ¶¶ 75, 82; (3) Relator's own citizen petitions submitted to FDA, *id.* ¶¶ 76-78; (4) FDA's November 2015 Advisory Committee meeting in which Relator participated, *id.* ¶¶ 85, 90; (5) Relator's adverse events "research" involving human patients and his study involving

mice published in 2016, *id.* ¶¶ 72-74, 77, 85, 91; and (6) FDA statements made in connection with labeling changes, *id.* ¶¶ 92, 94-95. Once again, that reliance dooms Relator's case because, as this Court explained in dismissing the FAC, "FDA was aware of all of [this] safety information concerning Cipro . . . because that information was either in an FDA document or presented to the FDA." *Bennett I*, 2022 WL 970219, at *10.[6]

The SAC does not identify *any* new sources of safety information that were not cited in the FAC. In particular, Relator's allegations about Defendants' failures to both "disaggregate" or "aggregate" data are not new. To support his "disaggregation" allegations, Relator pasted into the SAC virtually the same Levaquin adverse events chart—with the same 20+ "psychiatric adverse event[s]," percentages of FAERS cases containing the specific adverse events, and "yes" or "no" as to whether the specific psychiatric adverse event type was listed in the Levaquin "warnings and precautions" label section—that he included in his September 2014 citizen petition. *Compare* SAC ¶ 61 *with* Ex. D at 3. And with respect to Relator's allegation that "Defendants" "failed to aggregate the six symptoms that the FDA determined made up the operational definition of FQAD," SAC ¶ 63, per Relator's own allegations, FDA convened an Advisory Committee meeting in 2015 in which FQAD was discussed at length, *id.* ¶ 85. And, years later, in rejecting Relator's 2019 citizen petition, FDA indicated that the labeling "already addresses" the "adverse events from different body systems" that comprise FQAD and pointed out that FQAD "is not accepted medical terminology and is not used in clinical practice." Ex. L, 2020 FDA Decision at 1 n.2, 5-7.

[6] Relator baldly asserts that Bayer "should have submitted reports of adverse side effects of Cipro on at least quarterly basis—but did not." SAC ¶ 102. Setting aside that this new unparticularized allegation contradicts Relator's prior allegations in the FAC, *see* FAC ¶ 101-103, it is coupled with allegations that demonstrate *immateriality*—namely, Relator's disclosures: (1) in his 2014 citizen petitions of the same "serious side effects intentionally undisclosed by Defendants," SAC ¶ 76, and (2) that the 2013 FDA Study had featured "the very same side effects Relator's research had uncovered," SAC ¶ 75—all while CMS continued to reimburse claims for Cipro.

Therefore, because Relator "alleges the Government had knowledge yet provides no evidence that the Government stopped making payments or refused to make payments after gaining such knowledge," his pleading "establish[es] conclusively the *lack* of materiality," and must be dismissed. *Hlywiak*, 2022 WL 787957, at *11; *see also U.S. ex rel. DiLello v. Hackensack Meridian Health*, No. 20-cv-2949, 2022 WL 1284734, at *8 (D.N.J. Apr. 29, 2022) (dismissing for failure to plead materiality because inference drawn from complaint was that CMS consistently reimbursed claims despite knowledge of alleged noncompliance).

Relator complains that when FDA required updated Cipro labeling in 2016, "[n]o warning describing FQAD symptoms was added despite the numerous research studies conducted by [Relator] and the FDA's own [researcher] and numerous patients testifying before the FDA committees." SAC ¶¶ 92, 94. Relator attributes this to Defendants' alleged failure to "provide[] the full truth and non-manipulated data," *id.* ¶ 93, but he fails to identify *any* information that FDA did not possess—let alone information that Bayer and Merck possessed but concealed from FDA. Similarly, Relator acknowledges that, when FDA updated Cipro's labeling in 2018 to include "more prominent and consistent warnings regarding mental health side effects," it did so based on information Relator "had been . . . reporting to the FDA for years." *Id.* ¶ 95 (emphasis omitted).

Because FDA had knowledge of the safety information alleged in the SAC, including FQAD, mitochondrial toxicity, and psychiatric effects, its "real-world" decision to maintain approval for Cipro—which, in turn, caused CMS to continue to pay claims for the medication—prevents Relator from plausibly pleading materiality. *See Plavix*, 332 F. Supp. 3d at 959. "To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *Bennett I*, 2022 WL 970219,

at *10 (quoting *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016)). "The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory warnings." *Id.* (quoting *D'Agostino*, 845 F.3d at 8). If a private citizen believes federal "laws and regulations are inadequate to protect patients, it falls to the other branches of government to" address such concerns; "a False Claims Act suit is not the appropriate way to address them." *Petratos*, 855 F.3d at 494.

Further, as this Court explained in dismissing the FAC, FDA's Cipro labeling changes "cut[] further against materiality" because "FDA made [those] labeling changes *based on the same information* that Bayer . . . allegedly failed to disclose—yet the FDA conspicuously declined to include the side effects that Relator faults Bayer . . . for not including." *Bennett I*, 2022 WL 970219, at *10. Rather than address this aspect of the Court's ruling in his amended pleading, Relator has opted to ignore it. To that end, the SAC conveniently, and misleadingly, omits that, in FDA's assessment of safety information related to Cipro, FDA expressly rejected many of Relator's allegations. For example, Relator alleges that FDA would have included warnings about mitochondrial toxicity but for Defendants' alleged concealment, SAC ¶¶ 40, 97, but FDA *denied* his first petition because it concluded after a careful assessment that "[l]anguage regarding mitochondrial toxicity is not appropriate for inclusion in the *Warnings and Precautions* section or a boxed warning in a label." Ex. H, 2016 FDA Decision at 10. FDA explained that such language would "not help a clinician or patient identify or treat a particular adverse reaction." *Id.* at 7. Similarly, FDA rejected certain of Relator's requests in his second citizen petition due to a "lack of reasonable evidence" and declined to make Relator's suggested changes to Cipro's boxed warning. Ex. J, 2018 FDA Decision at 6-10, 12. FDA also rejected the additional labeling changes related to "FQAD" and psychiatric adverse events Relator sought in his third citizen petition

because, in FDA's view, "FQAD" does not reflect "accepted medical terminology and is not used in clinical practice." Ex. L, 2020 FDA Decision at 1 n.2, 5-7.

As this Court held on the same judicially noticed record, "FDA, with all the information alleged in the Amended Complaint, appears to have made a conscious decision not to include certain side effects in the label[] for Cipro." *Bennett I*, 2022 WL 970219, at *10. "Thus, while the FDA's changes 'show that the FDA was paying attention,' the 'lack of any further action also shows that the FDA viewed the information, including that furnished by Relator[], differently than Relator[] do[es].'" *Id.* (quoting *Nargol*, 865 F.3d 29) (alterations in original); *see also U.S. ex rel. Yu v. Grifols USA*, LLC, No. 1:17-CV-2226, 2021 WL 5827047, at *9, *12 (S.D.N.Y. Dec. 8, 2021) (dismissing for failure to plead materiality because "FDA has had a significant period of time to investigate and withdraw its approval, but has not done so" and there is "no basis . . . to supplant the FDA's decision-making with that of a court or jury"). Indeed, in stark contrast to Relator's assertion that FDA would never have approved Cipro had it known of the safety information alleged in the SAC, FDA explained in denying his third citizen petition that "[e]ven with the serious risks associated with [the product]," fluoroquinolones "may be an appropriate choice for a patient," and "it is important that certain patients have immediate access to" these medications. Ex. L, 2020 FDA Decision at 7-8. "FDA's failure actually to withdraw its approval of [Cipro] in the face of [Relator's] allegations precludes [him] from resting his claims on a contention that the FDA's approval was fraudulently obtained." *D'Agostino*, 845 F.3d at 8. The Court should dismiss the SAC for failure plausibly to plead materiality.

B. Relator Fails to Plead a Fraudulent Inducement Theory With Plausibility or Particularity.

The Court should dismiss the SAC for the independent reason that Relator's new theory of liability—fraudulent inducement—is not legally viable in this context. And even if it were, Relator

has failed to plead two essential elements of a fraudulent inducement FCA claim—falsity and causation—plausibly and with sufficient particularity.

1. The Fraudulent Inducement Theory Does Not Apply in the Absence of a Contractual Relationship.

The Third Circuit has not recognized a fraudulent inducement theory under the FCA in the absence of a direct contractual relationship between the defendant and the government. And a recent decision in this District refused to extend that theory, fashioned for "*contracts* induced by fraud," to "non-contract interactions with government regulatory bodies." *Plavix*, 332 F. Supp. 3d at 952. Recognizing that "[t]he [FCA] is not an all-purpose antifraud statute," *Escobar*, 579 U.S. at 194 (citation omitted), the *Plavix* court concluded that "embracing [a fraudulent inducement] theory [outside of the contract context] would be a step toward bringing all misrepresentations to government bodies within the purview of the FCA[,]" but "the FCA was not designed to have so expansive a scope." 332 F. Supp. 3d at 953. Following *Plavix*, another district court recently reached the same conclusion, and dismissed a fraudulent inducement FCA claim in the FDA-approval context because "there is no support for Relator's theory that the fraudulent inducement theory is applicable to cases where the parties did not enter into a contract." *Yu*, 2021 WL 5827047, at *10. Accordingly, this Court should dismiss the SAC because Relator's fraudulent inducement claim—the only liability theory he purports now to offer—simply does not apply here.

2. Relator Fails to Plead Falsity Plausibly and with Sufficient Particularity.

Even if Relator's theory were legally tenable in this context, his allegations are woefully inadequate because they fail sufficiently to plead falsity. Fraudulent inducement requires an "original fraudulent misrepresentation." *Bennett I*, 2022 WL 970219, at *6 (quoting *U.S. ex rel. Brown v. Pfizer, Inc.*, No. 05-cv-6795, 2017 WL 1344365, at *9 (E.D. Pa. Apr. 12, 2017)). And the circumstances of that original misrepresentation—the "who, what, when, where and how"—

must be pled with sufficient particularity to satisfy Rule 9(b)'s heightened pleading standard for FCA claims. *U.S. ex rel. Judd v. Quest Diagnostics Inc.*, 638 F. App'x 162, 168 (3d Cir. 2015). Failure to plead these particulars requires dismissal. *See United States v. C. Abbonizio Contractors, Inc.*, No. 20-cv-6573, 2021 WL 1138145, at *6 (D.N.J. Mar. 24, 2021) (dismissing fraudulent inducement claim because "complaint is lacking in facts regarding . . . alleged pre-bid communications"); *U.S. ex rel. Tessitore v. Infomedics, Inc.*, 847 F. Supp. 2d 256, 265 (D. Mass. 2012) (dismissing fraudulent inducement claim related to FDA approval for failure to plead initial misrepresentations); *U.S. ex rel. Feldstein v. Organon, Inc.*, No. 07-cv-2690, 2009 WL 961267, at *11 (D.N.J. Apr. 7, 2009) (dismissing complaint because relator failed to plead any details regarding misrepresentations "when [the manufacturer] obtained [FDA] approval").

Here, Relator has not plausibly pled—let alone pled with sufficient particularity—that Bayer or Merck made *any* initial false representation to FDA to get Cipro approved. Indeed, ignoring the Court's guidance in its opinion dismissing the FAC, Relator has not mustered a single fact of which Bayer or Merck was aware but concealed from FDA. Instead, the SAC simply includes phrases like "Defendants[7] have concealed and withheld information," *e.g.,* SAC ¶ 25, but those broad and vague assertions are nowhere combined with any particularized factual allegations. Rather, Relator assumes that Bayer and Merck *must* have concealed safety information from FDA because additional safety information was identified decades after Cipro's approval. This sort of speculation plainly is insufficient to plausibly plead falsity. As the court

[7] Like the FAC, the SAC uses the terms "Defendants," without identifying which defendants took which alleged actions—a defect that itself requires dismissal. *Bennett I*, 2022 WL 970219, at *7. In addition, other than the caption itself, Relator mentions Merck only twice in the entire SAC—once in paragraph 1 identifying Merck as a party and once in paragraph 27 identifying Merck as "a United States company based in New Jersey." SAC ¶¶ 1, 27. Because the SAC does not contain a single substantive allegation specific to Merck, Relator's claims against Merck should be dismissed for that reason alone.

noted in *Tessitore*, such an argument is "fallacious insofar as it presumes [defendant's] prior [misrepresentations] from . . . subsequent[ly]" discovered safety information. 847 F. Supp. 2d at 265.

To hold otherwise would turn the FCA into a "back-door regulatory regime," *U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 620 (2d Cir. 2016), under which any private citizen could second-guess a governmental agency's decision by asserting, without any factual support, that the agency must have been tricked into taking the action it did. Relator may quarrel with FDA's regulatory decisions related to Cipro, but his personal disagreement with FDA's conclusions is no basis for an FCA lawsuit. As the court held in *Plavix*, the FCA does not allow Relator to "reconsider and . . . reverse [FDA's] regulatory ruling on a basis that the agency itself explicitly has chosen not to act upon." 332 F. Supp. 3d at 959. Absent specific factual allegations that Bayer or Merck made misrepresentations or false statements upon which FDA relied in approving Cipro, Relator cannot plead falsity under a fraudulent inducement theory.

Feldstein is particularly instructive here. There, the court dismissed a relator's fraudulent inducement FCA claim because he simply "assume[d] that [the defendant] knew something and did not inform the FDA," but he "d[id] not detail any concrete evidence that support[ed] his allegations." 2009 WL 961267, at *11. The court reasoned that, without "reports or test results or other documentation showing that [the d]efendants knew" about and concealed serious adverse events, the relator's allegations were "highly speculative and insufficiently pleaded to satisfy [Rule] 9(b)." *Id.* Here too, *Tessitore* is instructive. There, the court dismissed a fraudulent inducement FCA claim where the complaint "d[id] not . . . identify who within [defendant] made allegedly false statements to the FDA and/or who . . . was involved in the alleged concealment

scheme[,] [n]or d[id] it provide information concerning any internal . . . procedures or policies on FDA submissions or the content of any actual [FDA] submission." 847 F. Supp. 2d at 265.

Here, eight years after his first citizen petition and five years after he first filed a complaint in this action, Relator's second amended pleading remains devoid of a single specific misrepresentation that Bayer or Merck made to FDA. The most Relator can muster is that "Bayer intentionally disaggregated individual symptomatic components of serious multi-system syndromes in its NDA," and also did the opposite by "fail[ing] to aggregate the . . . symptoms that . . . ma[k]e up the operational definition of FQAD." SAC ¶¶ 57, 63. But Relator's disaggregation/failure to aggregate assertions are internally inconsistent, vague, conclusory, and entirely speculative. As an initial matter, Relator uses the terms "disaggregate" and "failure to aggregate" apparently interchangeably, but they are polar opposites in meaning. *Compare id.* ¶ 57 *with id.* ¶ 63. And nowhere in the SAC does Relator pair these inconsistent statements with any specific allegations regarding unlawful pre- (or even post-) approval conduct by Bayer or Merck—let alone supply the particularity that Rule 9(b) demands. Indeed, Relator does not even allege that Bayer's supposed disaggregation/failure to aggregate violated any law or regulation concerning how data must be presented in an NDA, *see generally* 21 C.F.R. § 314.50, or that Bayer was *even aware* of facts to suggest that FDA wanted the side effects to be presented differently, especially given FDA's knowledge of the specific adverse events. Thus, Relator's allegations fall well short of Rule 12(b)(6)'s plausibility standard, as well as Rule 9(b)'s more demanding requirements.

3. Relator Fails to Plead But-For Causation.

Relator's claims fail for the additional reason that his new theory of liability lacks plausible and specific allegations of causation, another element of FCA liability. To plead an FCA claim based on fraudulent inducement, a relator must plead but-for causation. *U.S. ex rel. Thomas v. Siemens AG*, 991 F. Supp. 2d 540, 571 (E.D. Pa.), *aff'd*, 593 F. App'x 139 (3d Cir. 2014). "[T]hat

means [Relator] would have to provide sufficient facts for the court to draw a reasonable inference that [Bayer's] [alleged misrepresentations] caused [FDA] to" approve Cipro. *U.S. ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412, 420-21 (D.C. Cir. 2021). But Relator cannot clear that hurdle because of the same fatal deficiencies already discussed: He provides no details regarding any actual misrepresentation, let alone what its effect would have been on FDA. Moreover, FDA's failure to withdraw approval for Cipro even after learning "the full extent" of its adverse events (the same events Bayer allegedly concealed), *see* SAC ¶ 104, demonstrates that the supposed misrepresentations would *not* have changed FDA's approval decision. As the court explained in *D'Agostino*, the but-for causation requirement is one reason a "fraud-on-the-FDA theory [is] futile" absent "official agency action" reflecting the agency's agreement with the relator's position. 845 F.3d at 9. Accordingly, the Court should also dismiss for failure to plead causation.

C. The Court Should Dismiss Relator's Conclusory Off-Label Marketing Claim.

In dismissing the FAC, the Court rejected Relator's off-label marketing allegations, asserted then solely against the J&J Defendants, as "conclusory at best," "offer[ing] little on how the alleged off-label use constitutes fraud against the United States," and failing to allege "the who, what, when, where and how of the events at issue.'" *Bennett I*, 2022 WL 970219, at *11. The SAC now includes similarly "conclusory at best" allegations that Bayer and Merck promoted Cipro off label:

> From 2012 to present, and possibly previously, Bayer promoted and encouraged physicians to use Cipro for off-label purposes and caused fraudulent claims to be submitted to Medicaid and Medicare for millions of preventable or inappropriate services for individuals who consumed misbranded Cipro prescriptions or who used Cipro unknowingly for off-label purposes, the exact number yet to be determined.

SAC ¶ 13; *see also* SAC ¶ 15. This allegation falls woefully short of Rule 9(b)'s particularity requirement. *See Bennett I*, 2022 WL 970219, at *11; *U.S. ex rel. Travis v. Gilead Scis., Inc.*, No.

17-cv-1183, 2022 WL 991382, at *8 (E.D. Pa. Apr. 1, 2022); *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 519 (E.D. Pa. 2015).

III. The SAC Should Be Dismissed Under the FCA's Public Disclosure Bar

The FCA's "public disclosure bar" is a statutory mechanism that prevents private parties from bringing *qui tam* actions "when the relevant information has already entered the public domain through certain channels." *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 285 (2010). Congress enacted the bar to prevent the government from paying a *qui tam* bounty to private citizens who bring "suits which the government is capable of pursuing itself." *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 522 (3d Cir. 2007).

The current version of the bar provides that a *qui tam* action must be dismissed "if substantially the same allegations or transactions as alleged in the action" were "publicly disclosed" in "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," "a . . . Federal report, hearing, audit, or investigation," or "from the news media" before the relator filed his suit. 31 U.S.C. § 3730(e)(4)(A). To determine whether the public disclosure bar applies, courts assess first whether the information was disclosed through qualifying sources and then whether the relator's allegations are substantially similar to the information in the prior public disclosures. *See Atkinson*, 473 F.3d at 519. If each of these requirements is met, the bar applies, and the relator can avoid dismissal only if he is an "original source." 31 U.S.C. § 3730(e)(4)(A).

In *Bennett I*, this Court recognized that "the public disclosure bar prohibits relators from bringing claims based on publicly disclosed information that would be sufficient to state an FCA claim." *Bennett I*, 2022 WL 970219, at *5 n.2. But the Court questioned whether the bar applied here because "Relator cannot maintain a claim of fraud when considering the publicly disclosed information." *Id.* (citing *U.S. ex rel. Silver v. Omnicare, Inc.*, 903 F.3d 78, 86 (3d Cir. 2018)).

The public disclosure bar applies, however, even if the publicly available information does not actually allege fraud, and even if the relator's allegations are themselves insufficient to sustain an FCA claim. *Omnicare*, 903 F.3d at 83-84. Indeed, the bar applies as long as "substantially the same allegations *or transactions*" as the relator is alleging had already been "publicly disclosed" before the relator filed his action. 31 U.S.C. § 3730(e)(4)(A) (emphasis added). As the Third Circuit explained in *Omnicare*, "whereas an 'allegation' of fraud is a specific allegation of wrongdoing, a 'transaction' that raises an inference of fraud consists of both the allegedly misrepresented facts and the allegedly true state of affairs." 893 F.3d at 83. "To determine whether a fraudulent transaction has been publicly disclosed . . . , [the Third Circuit] employs a formula of sorts . . . : 'If X + Y = Z, Z represents the allegation of fraud and X [the allegedly misrepresented state of facts] and Y [the allegedly true state of facts] represent its essential elements, the fraudulent transaction [is] publicly disclosed [where] the combination of X and Y [is] revealed, from which readers or listeners may infer Z." *Id.* at 83-84 (citations omitted).

As discussed further below, the allegedly misrepresented state of facts is that Cipro's side effects have been properly disclosed to FDA and are adequately reflected in the product's labeling; that has been publicly disclosed through numerous sources, nearly all of which were generated by the government itself before Relator filed this suit. *See, e.g.*, Ex. L at 7 (product labeling adequately communicates Cipro's risks and benefits). The allegedly true state of facts—that Cipro's risks are not adequately disclosed on the product's labeling—was also publicly disclosed in various reports, Relator's citizen petitions, and through Relator's media appearances. *See, e.g.*, SAC ¶ 79 (alleging that Relator appeared on television to discuss the "undisclosed symptoms of FQ use"). Relator cannot avoid the public disclosure bar simply because the public disclosures did not explicitly allege that Bayer and Merck *fraudulently* concealed information from FDA. *See*

U.S. ex rel. Solomon v. Lockheed Martin Corp., 878 F.3d 139, 145 (5th Cir. 2017) ("When the elements of a fraudulent transaction are present in public disclosures, those public disclosures need not allege fraud in explicit language.").

In addition, because the bar may apply where the public disclosures do not allege fraud *at all*, there is no requirement that the publicly available information be "sufficient to state an FCA claim." *Bennett I*, 2022 WL 970219, at *5 n.2. *Omnicare* did not hold to the contrary. There, the public disclosures "merely indicate[d] the *possibility* that . . . fraud could be perpetrated in the . . . industry" generally—"an *allegation* that would alone be insufficient to state a claim for fraud under the FCA." 903 F.3d at 86 (emphases added). The Third Circuit held that such generalized allegations did not sufficiently raise an inference that "[the defendant] *in particular* was actually engaged in" the misconduct and therefore did not trigger the bar. *Id.* (emphasis added). Here, in contrast, the public disclosures reflect allegedly fraudulent *transactions* involving the specific product at issue in the SAC—Cipro. Further, the fact that Relator has not adequately pled a FCA violation in his complaint does not affect the bar's applicability. *See, e.g.*, *U.S. ex rel. Jehl v. GGNSC Southaven, LLC*, No. 19-cv-091, 2022 WL 983644, at *5-7 (N.D. Miss. Mar. 30, 2022) (dismissing FCA claims for lack of falsity or materiality and holding that claims would also be barred by the public disclosure bar); *U.S. ex rel. Gage v. Aviation*, No. 12-cv-904, 2014 WL 3007201, at *6 (W.D. Tex. July 2, 2014) (similar); *U.S. ex rel. Moore v. Cardinal Fin. Co., L.P.*, No. 12-cv-1824, 2017 WL 1165952, at *14 (D. Md. Mar. 28, 2017) (similar).

A. The Facts Underlying Relator's FCA Claims Were Publicly Disclosed Through Numerous Statutorily Enumerated Sources Before Relator Filed Suit.

The information Relator now seeks to characterize as an FCA violation was already publicly disclosed years before he filed this lawsuit, including in FDA's April 2013 report, his own 2014 citizen petitions, the 2015 FDA Advisory Committee briefing materials and public transcript,

numerous FDA press releases, through the news media, and in FDA's decisions on Relator's citizen petitions. Disclosure through each of these sources—and, certainly, the combined set of disclosures—triggers the public disclosure bar.

First, the 2013 FDA report, the 2015 Advisory Committee meeting documents, and FDA press releases are "[f]ederal report[s]" under the FCA's public disclosure bar. *See* 31 U.S.C. § 3730(e)(4)(A)(ii); *see U.S. ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 692-93 (8th Cir. 2014) (FDA reports were public disclosures); *see also Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 407-08 (2011) ("'report' is 'something that gives information' or a 'notification'").

Second, Relator's citizen petitions and FDA's decisions on those petitions are disclosures in federal administrative hearings. The term "hearing" under the FCA is "synonymous with 'proceeding,'" so public filings in connection with judicial or administrative proceedings are public disclosures. *U.S. ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 113 (1st Cir. 2010). Here, Relator's citizen petitions and FDA's decisions were publicly docketed and are publicly available on *regulations.gov*, *see* 21 C.F.R. § 10.30(e), and there is no question that they are, therefore, public disclosures. *See Amphastar Pharms. Inc. v. Aventis Pharma SA*, No. 09-cv-0023, 2012 WL 5512466, at *5 (C.D. Cal. Nov. 14, 2012) (response to citizen petition is public disclosure); *see also U.S. ex rel. Hartwig v. Medtronic, Inc.*, No. 11-cv-413, 2014 WL 1324339, at *9 (S.D. Miss. Mar. 31, 2014).

Third, as Relator himself admits, his allegations were also disclosed publicly through the news media—including through his own efforts—prior to his filing this action. Relator alleges that he "discussed his research of the *undisclosed* symptoms of FQ use on television news outlets." SAC ¶ 79 (emphasis added); *see, e.g.*, CBS 4 Miami, *Powerful Antibiotic Could Be a Prescription for Danger* (Feb. 13, 2015), https://cbsloc.al/3rwuxqe. Prior to his filing, there also were numerous

news articles available publicly that discussed Relator's citizen petitions, the November 2015 Advisory Committee meeting, and FDA's press releases and related labeling changes. Each of these qualifies as a public disclosure through the news media. *See Schindler Elevator*, 563 U.S. at 409 (public disclosure bar's "reference to 'news media' . . . suggests a . . . broad[] scope"); *see also U.S. ex rel. Moore v. Majestic Blue Fishers, LLC*, 812 F.3d 294, 302 (3d Cir. 2016).

B. Relator's Allegations Are Substantially Similar to the Information in the Public Disclosures.

Relator's allegations are "substantially similar" to the information in these numerous public disclosures. Indeed, much of the SAC simply recites information from these publicly available materials. *See, e.g.*, SAC ¶¶ 70-95. The numerous public disclosures discussed at length not only the adverse events with which Relator takes issue in his pleading (e.g., FQAD, mitochondrial toxicity, and psychiatric events), but also whether the then-existing Cipro labeling adequately disclosed the risks—precisely the claim Relator mirrors here. *See, e.g.*, Ex. A, 2013 FDA Report at 3 (peripheral neuropathy), 11-12 (mitochondrial toxicity); Ex. C, June 2014 Citizen Petition at 1-2 (mitochondrial toxicity); Ex. D, September 2014 Citizen Petition at 1-2 (psychiatric side effects); Exs. E, F, 2015 FDA Briefing and Transcript (FQAD); Ex. H, 2016 FDA Final Decision at 7, 10, 13 (mitochondrial toxicity).

These public disclosures were certainly sufficient to "set the government on the trail" of supposed non-disclosure of adverse event information. *See U.S. ex rel. Schumann v. AstraZeneca PLC*, No. 03-cv-5423, 2010 WL 4025904, at *5 (E.D. Pa. Oct. 13, 2010). Indeed, based largely on the public disclosures, the government assessed the relevant safety information and required updates to the Cipro label. The SAC "essentially parrots . . . the concerns outlined in [FDA reports]; tracks the public debate surrounding the issue [of the adequacy of the Cipro label]; and borrows heavily from [FDA's] publicly disclosed concerns with the [labeling]." *U.S. ex rel. Black*

v. Health & Hosp. Corp. of Marion Cty., 494 F. App'x 285, 295 (4th Cir. 2012) (brackets and quotation marks omitted). Relator's claims are precisely the type for which the public disclosure bar was designed.

C. Relator is Not an Original Source.

Relator cannot avoid dismissal under the public disclosure bar by claiming that he is an "original source," as his allegations are neither "independent of" nor "materially add[] to the publicly disclosed allegations or transactions." *See* 31 U.S.C. § 3730(e)(4)(B). To qualify as an original source, "[a] relator cannot 'merely mirror allegations that were already publicly disclosed.'" *U.S. ex rel. Sirls v. Kindred Healthcare, Inc.*, 517 F. Supp. 3d 367, 386 (E.D. Pa. 2021) (quoting *Omnicare*, 903 F.3d at 92). To the contrary, a relator can satisfy the original source exception only "when [he] contributes information—*distinct from what was publicly disclosed*—that adds in a significant way to the essential factual background: 'the who, what, when, where and how of the events at issue.'" *Moore*, 812 F.3d at 307 (quoting *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 218 (3d Cir. 2002)) (emphasis added). In other words, a *qui tam* complaint must provide "genuine, useful information that the government lacks." *In re Nat. Gas Royalties Qui Tam Litig. (CO2 Appeals)*, 566 F.3d 956, 961 (10th Cir. 2009).

Relator cannot meet this test. The SAC adds nothing to the information that had been publicly disclosed well before Relator filed this action. Instead, the SAC simply repackages that same information, alleging that Cipro may cause certain side effects and that the drug's labeling did not adequately warn of that risk. Nowhere in the SAC does Relator offer previously undisclosed information reflecting the "who, what, when, where and how" of any alleged fraud. *See Moore*, 812 F.3d at 307.

IV. The Court Should Dismiss This Action With Prejudice.

This is now Relator's third attempt to plead a FCA violation. The Third Circuit has instructed that district courts may dismiss with prejudice "where the plaintiff was put on notice as to the deficiencies in his complaint, but chose not to resolve them." *Krantz v. Prudential Invs.*, 305 F.3d 140, 144 (3d Cir. 2002); *see Gasoline Sales, Inc. v. Aero Oil Co.*, 39 F.3d 70, 74 (3d Cir. 1994) (affirming denial of leave to amend because "three attempts at a proper pleading is enough"); *see also Maldonado v. City of Passaic Bd. of Educ.*, No. 17-cv-12245, 2020 WL 289649, at *4 (D.N.J. Jan. 21, 2020). Relator has not cured, and cannot cure, the deficiencies the Court detailed in *Bennett I*—nearly all of which stem from Relator's admissions and facts that are conclusively established through documents subject to judicial notice. *See U.S. ex rel. Denis v. Medco Health Sols., Inc.*, 299 F. Supp. 3d 610, 617 (D. Del. 2017), *aff'd*, 777 F. App'x 30 (3d Cir. 2019) (dismissing FCA case under public disclosure bar and determining amendment would be futile when relator had failed to cure deficiencies after several pleading attempts). Accordingly, any further attempt to amend would be futile, and the Court should dismiss the SAC with prejudice.[8]

CONCLUSION

For all of these reasons, the Court should dismiss the SAC in its entirety with prejudice.

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[8] As in numerous other cases, Relator's state law claims fail for the same reasons as his federal FCA claims. *See, e.g.*, *Plavix*, 332 F. Supp. 3d at 960; *Podgoretsky v. Ocwen Loan Serv. LLC*, No. 14-cv-239, 2014 WL 12524654, at *2 (E.D. Va. Aug. 19, 2014). Relator's claims under the New Mexico FCA should be dismissed for the additional reason that he lacks statutory standing. *See* N.M. Stat. 27-14-7(B), E(2). At a minimum, the Court should decline to exercise supplemental jurisdiction over Relator's state law claims. *See Bennett I*, 2022 WL 970219, at *11.

Respectfully Submitted,

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